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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

In re Gabapentin Patent Litigation  

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)  
) MDL No. 1384  
) Master Docket No.  
) 00-CV-2931 (FSH)  
)  
) **This Filing Applies To:**  
) Teva Defendants  
) C.A. No. 00-CV-4168 (FSH)  
) C.A. No. 00-CV-4589 (FSH)  
)  
) IVAX Defendants  
) C.A. No. 00-CV-6073 (FSH)  
) C.A. No. 01-CV-0193 (FSH)  
) C.A. No. 01-CV-1537 (FSH)  
)  
) Eon Defendants  
) C.A. No. 01-CV-2194 (FSH)  
)

**NOTICE OF MOTION TO STRIKE CERTAIN AFFIRMATIVE DEFENSES  
OF TEVA, IVAX, AND EON DEFENDANTS**

TO: ALL COUNSEL ON ATTACHED SERVICE LIST

PLEASE TAKE NOTICE that on October 6, 2008 at 9:30 a.m., or as soon thereafter as counsel may be heard, or at such other date and time as the Court may set, Plaintiffs shall move before the Honorable Faith S. Hochberg, United States District Judge, sitting at the United States Post Office & Courthouse, 50 Walnut Street, Newark, New Jersey, for an Order granting Plaintiffs' Motion to Strike Certain Affirmative Defenses of Teva, IVAX, and Eon Defendants, along with such other and further relief as the Court deems just and proper.

PLEASE TAKE FURTHER NOTICE that, in support of this motion, Plaintiffs will rely on the Memorandum of Law and Declaration of John J. Francis, Jr. submitted herewith. A proposed Order accompanies this Motion.

PLEASE TAKE FURTHER NOTICE that Plaintiffs request oral argument if opposition is received.

Dated: June 16, 2008

/s/ John J. Francis, Jr.  
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**PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR  
MOTION TO STRIKE CERTAIN AFFIRMATIVE DEFENSES  
OF TEVA, IVAX, AND EON DEFENDANTS**

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**PRELIMINARY STATEMENT**

Plaintiffs Pfizer Inc., Warner-Lambert Company LLC, Gödecke GmbH, and Pfizer Pharmaceuticals LLC (collectively, “W-L”) brought these patent infringement cases asserting that defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, “Teva”); Zenith Laboratories, Inc. (now known as IVAX Pharmaceuticals NV, Inc.), Zenith Goldline Pharmaceuticals, Inc. (now known as IVAX Pharmaceuticals, Inc.), and IVAX Corp. (collectively, “IVAX”); and Eon Labs Manufacturing, Inc. (now known as Eon Labs, Inc.) and Sandoz, Inc. (collectively, “Eon,” and together with Teva and IVAX, “Defendants”) have infringed U.S. Patent No. 6,054,482 (the “‘482 Patent”) by their proposed (now actual) sale in the United States of generic versions of W-L’s patented Neurontin® product. Teva, IVAX, and Eon, along with the Purepac defendants, launched their generic gabapentin products at risk, before any court ruling on liability.

Now that the Federal Circuit has reversed the grant of summary judgment of non-infringement and Teva, IVAX, and Eon face potential liability for the damage they caused to W-L’s Neurontin® product, Defendants assert affirmative defenses in their Answers to W-L’s First Amended and Supplemental Complaints that have absolutely nothing to do with the infringement issue or the enforcement of the ‘482 Patent. Defendants also ignore the fact that they have not

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been harmed but instead have profited handsomely from their at-risk launches. Under the circumstances, it is not surprising that none of these defenses are viable as a matter of law.

Specifically, all three Defendants assert affirmative defenses of unclean hands, which rest entirely upon their allegations about W-L's alleged "off-label marketing" of Neurontin®. Yet, Defendants do not (and cannot) allege that W-L's marketing of Neurontin® had anything to do with W-L's enforcement of the '482 Patent in this litigation, much less allege that that marketing is "directly related" or "closed connected" to enforcement of the '482 Patent, as is required for unclean hands. Teva and IVAX – but not Eon – also allege that W-L engaged in patent misuse by purportedly delaying the prosecution of the '482 Patent, but they do not (and cannot) allege that those activities altered the physical or temporal scope of the '482 Patent, an essential element of patent misuse, or that W-L improperly negotiated to extend its patent term.

The allegations of unclean hands and patent misuse are insufficient as a matter of law. They should be stricken pursuant to Rule 12(f) to streamline the issues in these cases.

### **BACKGROUND**

W-L scientists discovered gabapentin in the 1970s, and obtained various patents covering gabapentin and certain uses of gabapentin. W-L could not produce a viable commercial product, however, because it discovered that gabapentin could become unstable and convert to toxic gabapentin lactam. Through further investigation, W-L determined that gabapentin products had to be essentially free from mineral acid impurities, and that certain adjuvants that can promote conversion of gabapentin to its corresponding lactam should be avoided. W-L applied for a U.S. patent on these inventions in 1990.

In late 1994, the Patent Office issued a notice of allowance of the 1990 application, setting an issue date in March 1995. In January 1995, however, W-L withdrew the application and filed a continuation application in order to specifically cite prior art U.S. Patent No. 4,152,326 (the “‘326 Patent”) to the examiner. Teva Ans. at ¶¶ 68-69; IVAX Ans. at ¶¶ 67-68.<sup>1</sup> After five more years of prosecution, the ‘482 Patent issued in April 2000. Teva Ans. at ¶ 14; IVAX Ans. at ¶ 15; Eon Ans. at ¶ 13.

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<sup>1</sup> The Answers of Teva, IVAX, and Eon to W-L’s First Amended and Supplemental Complaint will be referred to as “Teva Ans.,” “IVAX Ans.,” and “Eon Ans.,” respectively.

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Based on its discoveries, W-L developed its Neurontin® product. Following clinical trials, W-L submitted to the FDA its first New Drug Application (“NDA”), NDA No. 20-235, covering Neurontin® capsules, and NDA No. 20-882, covering Neurontin® tablets. Teva Ans. at ¶ 20; IVAX Ans. at ¶ 21. W-L’s first NDA was approved by the FDA in December 1993 (Teva Ans. at ¶ 47; IVAX Ans. at ¶ 46) and W-L started selling its Neurontin® capsules in early 1994.

Thereafter, Teva, IVAX, and Eon submitted to the FDA Abbreviated New Drug Applications (“ANDAs”) for gabapentin capsules and/or tablets. Teva Ans. at ¶¶ 21, 23 (capsules and tablets); IVAX Ans. at ¶¶ 22, 24 (capsules and tablets); Eon Ans. at ¶ 20 (capsules). All three Defendants’ ANDAs included paragraph IV certifications pursuant to the Federal Food Drug and Cosmetic Act that W-L’s ‘482 Patent was invalid or not infringed. *See* Teva Ans. at ¶¶ 21, 23; IVAX Ans. at ¶¶ 22, 24; Eon Ans. at ¶ 20. *See also* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

W-L filed these lawsuits against Teva, IVAX, and Eon following Defendants’ paragraph IV certifications, seeking to enforce the ‘482 Patent. W-L filed Amended and Supplemental Complaints in April 2008, and Defendants have filed Answers to these complaints. This is W-L’s opening brief in support of its motion to strike certain affirmative defenses raised by Teva, IVAX and Eon in those Answers.

## **ARGUMENT**

### **I. THE APPLICABLE LEGAL STANDARDS**

Teva's and IVAX's Fourth and Fifth Affirmative Defenses (of unclean hands and patent misuse, respectively) and Eon's Fifth Affirmative Defense (of unclean hands) should be stricken from their Answers under Fed. R. Civ. P. 12(f). "A motion to strike under Rule 12(f), is the 'primary procedure' for objecting to an insufficient affirmative defense." *See United States v. Acorn Tech. Fund, L.P.*, C.A. No. 03-070, 2006 WL 237506, at \*4 (E.D. Pa. Jan. 31, 2006) (citation omitted). *See also* 2 James Wm. Moore, *Moore's Federal Practice* § 12.37[4] (3d ed. 2007) ("Because legal insufficiency is expressly included in Rule 12(f), a motion to strike is the proper means for attacking the legal insufficiency of a defense.").

This Court in *Eisai Co., Ltd. v. Teva Pharmaceuticals USA, Inc.*, 2008 WL 877966 (D.N.J. Feb. 13, 2008), provided a concise statement of the standard on a motion pursuant to Rule 12(f):

Fed. R. Civ. P. 12(f) allows a court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." The motion to strike an affirmative defense challenges the legal sufficiency of the pleading and is therefore governed by the same standard as a 12(b)(6) motion to dismiss. An affirmative defense is insufficient as a matter of law if it cannot succeed under any circumstances.

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*Id.* at \*2 (citations omitted). *See also Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955, 1965 (2007) (“*Twombly*”) (holding that to survive on a motion to dismiss under Rule 12(b)(6), “[f]actual allegations must be enough to raise a right to relief above the speculative level”); *Id.* at 1964-65 (“obligation to provide the ‘grounds’ of [pleading party’s] ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.”); *Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (same).

**II. DEFENDANTS’ UNCLEAN HANDS AFFIRMATIVE DEFENSES SHOULD BE STRICKEN BECAUSE DEFENDANTS HAVE NOT ALLEGED ANY RELATIONSHIP BETWEEN THE ALLEGED MISCONDUCT BY W-L AND THE RELIEF SOUGHT IN THIS ACTION.**

**A. Teva’s and IVAX’s Unclean Hands Affirmative Defenses Should Be Stricken.**

Teva’s and IVAX’s identical allegations of unclean hands focus exclusively on W-L’s alleged “illegal marketing program” and promotion of “off-label uses” for Neurontin®. Teva Ans. at ¶¶ 45-60; IVAX Ans. at ¶¶ 44-59. Although Teva and IVAX allege a variety of Neurontin®-related marketing activities by W-L in fifteen paragraphs, they make no attempt to tie those alleged acts to any issue pending before this Court. Specifically, Teva and IVAX allege that W-L refrained from seeking FDA approval for any non-epilepsy indications, purportedly because “[g]eneric equivalents may only be marketed for the same

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approved indications as NEURONTIN” and W-L allegedly “calculated that seeking non-epilepsy indications would allow generic equivalents to compete with a ‘son of Neurontin’ drug product” that W-L hoped would be approved for both epilepsy and non-epilepsy uses. Teva Ans. at ¶ 55; IVAX Ans. at ¶ 54. Teva and IVAX then allege in conclusory fashion:

Warner-Lambert’s admitted illegal and fraudulent promotion of NEURONTIN for unapproved uses—undertaken in part to limit competition from generic gabapentin products—constitutes unclean hands. Because of Warner-Lambert’s unclean hands, Plaintiffs should be denied the injunctive and other equitable relief requested in the Amended Complaint.

Teva Ans. at ¶ 60; IVAX Ans. at ¶ 59. Nowhere in their unclean hands allegations do Teva or IVAX even mention the ‘482 Patent, let alone attempt to tie their allegations to the enforcement of that patent.

Teva and IVAX have not alleged, and cannot allege, that the purported misconduct is directly related, much less “closely connected,” to the relief sought by W-L in this action (enforcement of the ‘482 Patent), as the law of unclean hands requires, or that the purported misconduct caused them any harm whatsoever. Thus, Teva and IVAX have failed to state an unclean hands defense.

The Third Circuit has stated that “the primary principle guiding application of the unclean hands doctrine is that the alleged inequitable conduct must be connected . . . to the matters before the court for resolution.” *In Re New*

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*Valley Corp.*, 181 F.3d 517, 525 (3d Cir. 1999). Although “[t]he maxim of unclean hands mandates that ‘he who comes into equity must come with clean hands,’” *Medpointe Healthcare Inc. v. Hi-Tech Pharmaceutical Co.*, 380 F. Supp. 2d 457, 463 (D.N.J. 2005), “courts of equity do not make the quality of the suitors the test.” *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245 (1933). Rather, the operative principle is that “the connection between the misconduct and the claim must be close.” *New Valley*, 181 F.3d at 525. “Only when ‘some unconscionable act of one coming for relief has immediate and necessary relation to the equity that’ the party seeks will the doctrine bar recovery.” *Id.* (quoting *Keystone*, 290 U.S. at 245).

Here, Teva and IVAX do not allege how W-L’s purported off-label marketing directly relates or is closely connected to W-L’s enforcement of the ‘482 Patent. They cannot because there is *no* such connection. Thus, Teva and IVAX wholly neglect to allege the “primary principle guiding application” of unclean hands – the “immediate and necessary relation” of the alleged bad acts to this litigation – and therefore fail to fulfill the pleading requirement of “‘stating . . . a claim . . . with enough factual matter (taken as true) to suggest’ the required element.” *Phillips*, 515 F.3d at 234 (quoting *Twombly*, 127 S.Ct. at 1965 (2007)).

In fact, then Magistrate Judge Chesler, during litigation relating to earlier Neurontin patents, denied a motion to compel discovery filed by the

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Purepac defendants regarding W-L's alleged off-label marketing of Neurontin® as irrelevant to their unclean hands defense. He explained that "[i]t is indeed clear that there are no cases which applied this doctrine to circumstances which are even close to that presented in this matter," and that an "assertion of an unclean hands defense under the circumstances contended" would make as much sense as an assertion "by which a careless motorist would be able to defend a subsequent personal injury suit by proving that the pedestrian had beaten his wife before leaving his home." Transcript of Motion Hearing at 32-33, *Pfizer v. PurePac/Faulding*, C.A. No. 98-2749 (JCL) (Dec. 27, 2000) (attached as Ex. A to accompanying Declaration of John J. Francis, Jr. ["Francis Declaration"]).

Additionally, in factually similar circumstances in a trademark infringement case, the Third Circuit in *Ciba-Geigy Corp. v. Bolar Pharmaceutical Co., Inc.* held that defendants' allegation of plaintiff's alleged sale of adulterated drug batches and violations of FDA marking regulations could not support a defense of unclean hands because they "do not relate to the subject matter of [plaintiff's trademark infringement] claim." 747 F.2d 844, 855 (3d Cir. 1984). *See also Medpointe*, 380 F. Supp. 2d at 465 ("Like the defendant's alleged misconduct in *CIBA-GEIGY* . . . the Court finds that, here, [plaintiff]'s alleged misconduct is also unrelated . . . because [it], at best, involves a failure to disclose a prior ruling on [a different] patent, and not on the [patent] actually involved in this case.").

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Furthermore, despite Teva's and IVAX's fifteen paragraphs of allegations relating to W-L's alleged improper marketing activities, they conclude by alleging only that W-L's actions were "undertaken in part to limit competition from generic gabapentin products." Teva Ans. at ¶ 60; IVAX Ans. at ¶ 59. This conclusory allegation does not state a defense because it is not supported by specific factual allegations. Teva and IVAX do not allege, for example, how W-L's alleged off-label marketing could or did *limit* competition in any way, much less how their allegations relate to these lawsuits alleging infringement of the '482 Patent.<sup>2</sup> Under *Twombly*, Teva and IVAX must make "[f]actual allegations [sufficient] to raise a right to relief above the speculative level." *Twombly*, 127 S.Ct. at 1965. They have not done that.

Finally, again assuming as true Teva's and IVAX's allegations of W-L's marketing misconduct, there is no allegation that they have anything to do with W-L's right to sue for infringement of the '482 Patent in this litigation. *See* Transcript of Motion Hearing at 33, *Pfizer v. PurePac/Faulding* (Ex. A to Francis

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<sup>2</sup> Defendants also do not allege that they have been precluded in any way from selling gabapentin for any use, nor could they make such an allegation because their products are freely substitutable for Neurontin®. Thus, Defendants have only benefited from any expansion of the market based on any alleged off-label uses.

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Declaration) (“What is material is not that the Plaintiff’s hands are dirty, but that he dirtied them in acquiring the right he now asserts or that the manner of dirtying renders inequitable the assertion of such rights against the Defendant.”). As noted above, the unclean hands allegations do not even mention the ‘482 Patent.

Because Teva and IVAX have not alleged any misconduct by W-L that gave rise to or affected the rights claimed by W-L in this litigation, their affirmative defenses of unclean hands should be stricken from their Answers.

**B. Eon’s Unclean Hands Affirmative Defense Should Be Stricken.**

Eon alleges even less than Teva and IVAX as a basis for unclean hands. Eon summarizes W-L’s alleged “illegal off-label marketing program” in only four paragraphs (Eon Ans. at ¶¶ 35-38). Eon then concludes in an identical manner to Teva and IVAX, stating:

Warner-Lambert’s admitted illegal and fraudulent promotion of NEURONTIN for unapproved uses—undertaken in part to limit competition from generic gabapentin products—constitutes unclean hands. Because of Warner-Lambert’s unclean hands, Plaintiffs should be denied the injunctive and other equitable relief requested in the Amended Complaint.

Eon Ans. at ¶ 39; Teva Ans. at ¶ 60; IVAX Ans. at ¶ 59. As with Teva and IVAX, Eon’s unclean hands allegations do not mention the ‘482 Patent.

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Eon's barebones defense includes little in the way of any details relating to the alleged "illegal off-label marketing program" or how this program was allegedly "undertaken in part to limit competition from generic gabapentin products . . . ." Under *Twombly*, Eon's "obligation to provide the 'grounds' of [its] 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." 127 S.Ct. at 1964-65. Beyond stating labels and conclusions, Eon makes no attempt to even plead the elements of a defense of unclean hands. And, as with Teva and IVAX, Eon does not connect the alleged misconduct to the matter seeking resolution in this Court – infringement of the '482 Patent – which is a prerequisite to a defense of unclean hands. *See New Valley*, 181 F.3d at 525.

The reasons that Teva and IVAX's unclean hands defense should be stricken apply *a fortiori* to Eon's pleading, and Eon's affirmative defense of unclean hands should be stricken from its Answer.

**III. TEVA AND IVAX HAVE FAILED TO ALLEGE AN AFFIRMATIVE DEFENSE OF PATENT MISUSE BECAUSE THEY HAVE NOT ALLEGED THAT ANY ACT BY W-L BROADENED THE PHYSICAL OR TEMPORAL SCOPE OF THE '482 PATENT.**

Teva and IVAX identically allege that W-L committed patent misuse by improperly delaying the issuance of the '482 Patent, first, by "repeatedly making the same arguments to the patent examiner" and "repeatedly filing

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continuation applications,” (Teva Ans. at ¶ 64; IVAX Ans. at ¶ 63) and, second, by failing to cite the ‘326 Patent in the first-filed application (Teva Ans. at ¶ 65; IVAX Ans. at ¶ 64) and then withdrawing its application so it could cite the ‘326 Patent in a continuation application. Teva Ans. at ¶¶ 68-69; IVAX Ans. at ¶¶ 67-68. According to Teva and IVAX:

By virtue of its intentional and unexcused delay, Warner-Lambert postponed both the issuance and expiration dates of the ‘482 patent. Warner-Lambert did so in order to forestall and enjoin generic competition for NEURONTIN for as long as possible, and in any event longer than it otherwise would have been able to had the ‘482 patent issued in 1995. This attempt to extend the temporal scope of patent protection for NEURONTIN constitutes patent misuse.

Teva Ans. at ¶ 72; IVAX Ans. at ¶ 71. According to Teva and IVAX, “[b]ut for this delay, the ‘270 application would have issued as a patent on March 7, 1995 instead of April 2000, the issue date of the ‘482 patent.” Teva Ans. at ¶ 71; IVAX Ans. at ¶ 70. Even accepting these allegations as true, however, Teva and IVAX have failed to state an affirmative defense of patent misuse.

To successfully assert patent misuse, an accused infringer must allege facts showing that the patentee “impermissibly broadened *the ‘physical or temporal scope’ of the patent grant* with anticompetitive effect.” *Windsurfing Int’l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001 (Fed. Cir. 1986) (emphasis added). “[I]n evaluating a patent misuse defense, ‘[t]he key inquiry is whether, by

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imposing conditions that derive their force *from the patent*, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect.” *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1341 (Fed. Cir. 2004) (emphasis added) (quoting *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998)); *B. Braun Medical v. Abbott Lab.*, 124 F.3d 1419, 1427 (Fed. Cir. 1997).

First, Teva and IVAX have not alleged, and cannot allege, that W-L improperly broadened the *physical* scope of the ‘482 Patent by imposing anticompetitive conditions on Teva, IVAX, or anyone else, such as by “us[ing] the patent as a . . . tool to restrain [trade practices] in areas not claimed under the patent.” *Medpointe*, 380 F. Supp. 2d at 467.<sup>3</sup>

Second, although Teva and IVAX claim that W-L extended the *temporal* scope of the ‘482 Patent, their allegations do not support this claim. Under *Twombly*, Teva and IVAX must plead “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action.” *Twombly*, 127

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<sup>3</sup> Such broadening typically occurs by “(1) requiring the purchase of unpatented goods for use with patented apparatus or processes, (2) prohibiting production or sale of competing goods, [or] (3) conditioning the granting of a license under one patent upon the acceptance of another and different license.” 6 Donald S. Chisum, *Patents* § 14.03[3], at 19-451 (2007).

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S.Ct. at 1965. Here, Teva and IVAX have not alleged and cannot allege that W-L expanded the temporal scope of the '482 Patent beyond the expiration date of the patent.<sup>4</sup> To the contrary, Teva and IVAX explicitly admit in their Answer that the '482 Patent “appears on its face to have issued on April 25, 2000, and to expire on April 25, 2017” – a term of 17 years. Teva Ans. at ¶ 14; IVAX Ans. at ¶ 15. Hence, even accepting as true for purposes of this motion that W-L delayed the issuance of the '482 Patent, the delay resulted in nothing more than a shift in the beginning and end dates of the 17-year patent term, not an extension of the temporal scope of the '482 Patent. W-L is not aware of any case where a court has found patent misuse in such circumstances.

Moreover, all of W-L's acts occurred before the '482 Patent issued; therefore, Teva and IVAX do not and cannot allege that W-L obtained this shift in the patent term improperly by “negotiat[ing] with the leverage of [the patent] monopoly.” *Aronson*, 440 U.S. at 265. “The policy of the patent misuse doctrine

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<sup>4</sup> Cases involving temporal expansions of a patent primarily concern situations where the patentee “negotiate[s] with the leverage of [the patent] monopoly” and “use[s] that leverage to project th[e] royalty payments beyond the life of the patent.” *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979) (quoting *Brulotte v. Thys Co.*, 379 U.S. 29, 32-34 (1964)). See also *Virginia Panel Corp. v. Mac Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997) (using “arrangements in which a patentee effectively extends the term of its patent by requiring post-expiration royalties” as an example of patent misuse).

16.

is ‘to prevent a patentee from using the patent to obtain market benefit beyond that which inures in the statutory patent right.’” *Monsanto*, 363 F.3d at 1341 (quoting *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 704 (Fed. Cir. 1992)). Teva and IVAX do not allege that, once the ‘482 Patent issued, W-L used or enforced the patent improperly.

Finally, Teva and IVAX are critical of W-L’s prosecution of the ‘482 Patent because W-L continued to seek allowance of its application over rejections by the Patent Office. However, the fact that the patent prosecution took ten years does not undermine its validity: “Multiple interviews are not illegal, and persistence in patent prosecution is not grist for patent invalidity.” *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997).

Because Teva and IVAX have not sufficiently alleged that W-L improperly broadened the physical or temporal scope of the ‘482 Patent, and have not alleged that W-L used the ‘482 Patent improperly in any way, Teva and IVAX have failed to state an affirmative defense of patent misuse.

**CONCLUSION**

For the foregoing reasons, W-L respectfully requests that the Court strike Teva's and IVAX's affirmative defenses of unclean hands and patent misuse and Eon's affirmative defense of unclean hands.

/s/ John J. Francis, Jr.

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June 16, 2008

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

In re Gabapentin Patent Litigation  
\_\_\_\_\_

)  
) MDL No. 1384  
) Master Docket No.  
) 00-CV-2931 (FSH)  
)  
) **This Filing Applies To:**  
) Teva Defendants  
) C.A. No. 00-CV-4168 (FSH)  
) C.A. No. 00-CV-4589 (FSH)  
)  
) IVAX Defendants  
) C.A. No. 00-CV-6073 (FSH)  
) C.A. No. 01-CV-0193 (FSH)  
) C.A. No. 01-CV-1537 (FSH)  
)  
) Eon Defendants  
) C.A. No. 01-CV-2194 (FSH)  
)

**DECLARATION OF JOHN J. FRANCIS, JR.  
IN SUPPORT OF MOTION TO STRIKE CERTAIN  
AFFIRMATIVE DEFENSES OF TEVA, IVAX, AND EON DEFENDANTS**

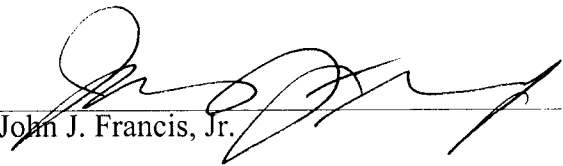
I, JOHN J. FRANCIS, JR., declare as follows:

1. I am Of Counsel at the law firm of Drinker Biddle & Reath LLP, counsel for Plaintiffs. I submit this Declaration in support of Plaintiffs' Motion to Strike Certain Affirmative Defenses of Teva, IVAX, and Eon Defendants. I am a member in good standing of the State Bar of New Jersey and this Court. I have personal knowledge of the information set forth in this Declaration.

2. Attached hereto as **Exhibit A** is a true and correct copy of relevant pages of the Transcript of Motion Hearing, *Pfizer v. PurePac/Faulding*, C.A. No. 98-2749 (JCL) (Dec. 27, 2000).

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: June 16, 2008

  
\_\_\_\_\_  
John J. Francis, Jr.

# **EXHIBIT A**

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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

Pfizer,  
Warner-Lambert,

Plaintiff(s).

V.

PurePac/Faulding,

Defendant(s).

.....

Docket #CV-98-2749 (JCL)

United States Courthouse  
Newark, New Jersey  
December 27, 2000

TRANSCRIPT OF MOTIONS HEARING  
BEFORE THE HONORABLE STANLEY R. CHESLER  
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

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1 THE COURT: Good morning everybody.

2 ALL: Good morning, Your Honor.

3 THE COURT: I guess we should put our appearances on  
4 the record and then settle in for a nice long session, folks.

5 MR. FRANCIS: For Warner Lambert and Pfizer, John  
6 Francis, Drinker, Biddle & Shanley. And with me is Mr.  
7 Barrett, Terry Barrett of Fitzpatrick, Cella, Harper & Scinto.

8 THE COURT: Good morning.

9 MR. FRANCIS: Also behind us are Dave Lorenz and Nancy  
10 Juett of Fitzpatrick, Cello. And behind them if I may, Judge,  
11 are two of my children, my daughter Carrie who's in her first  
12 year of law school, and my son, John.

13 THE COURT: Good morning. Hi.

14 MR. FRANCIS: Good morning, Your Honor.

15 THE COURT: Mr. Calmann?

16 MR. CALMANN: Good morning, Your Honor, Arnold  
17 Calmann, Saiber, Schlesinger, Satz & Goldstein for Faulding  
18 and PurePac. And I'll let counsel introduce themselves.  
19 You're familiar with them, Judge.

20 THE COURT: I could never forget them.

21 MR. HAUG: Good morning, Your Honor, Ed Haug. And on  
22 my left, Steve Amundson, Frommer, Lawrence & Haug for PurePac.  
23 And to Arnie's left, Brenda McGraf from Faulding. And behind  
24 us Terri Young an associate also with the firm.

25 THE COURT: Good morning to all of you. Mr. Haug,

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1 before we proceed, did you send me a letter indicating what you  
2 believe should be an appropriate agenda today?

3 MR. HAUG: No, Your Honor.

4 THE COURT: Okay. So all I've got is Warner Lambert's  
5 proposed agenda?

6 MR. HAUG: Yes, and I think it's a good one.

7 THE COURT: Fine.

8 MR. HAUG: And there are some details that will be  
9 added to it as we go along.

10 THE COURT: Okay. And I understand that all of you  
11 have gotten a copy of Judge Lifland's opinion on the various  
12 12(B)(6) and --

13 MR. FRANCIS: I received mine --

14 THE COURT: -- motions.

15 MR. FRANCIS: -- yesterday. Mr. Barrett has not. I  
16 gave him a copy this morning, but he hasn't had a chance to  
17 look at it.

18 MR. BARRETT: John filled me in on some highlights,  
19 Your Honor, so that I'm --

20 THE COURT: Let me put it this way. The main  
21 highlight seems to be bifurcation of the non-patent claims, and  
22 dismissal of the PurePac DJ action, if I recall correctly.

23 MR. FRANCIS: I think that's right, Your Honor. And  
24 that last aspect of it, the dismissal of the declaratory  
25 judgment action, it seems to me removes a great part if not all

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1 of the controversy that we've had over the Order of  
2 Consolidation.

3 THE COURT: That's what hit me. Would that  
4 essentially be correct?

5 MR. CALMANN: I don't think so, Your Honor.

6 THE COURT: And why so? I'm just curious.

7 MR. CALMANN: There are two cases that remain, Your  
8 Honor, one of which was filed on June 15 after receiving notice  
9 on June 14. Warner Lambert takes the position that that case  
10 is not a Hatch Waxman case, but the later case is. Why would  
11 they take that position? Because by taking the later position  
12 they have 30 months stay at a much later point, and that  
13 further extends the monopoly that we have asserted that Judge  
14 Lifland has found summary judgment should be denied on.

15 MR. FRANCIS: With the dismissal of the declaratory  
16 judgment action, the only cases that exist on the Lactam free  
17 patents are both suits filed by Warner Lambert. The first one  
18 that we filed is to avoid a problem on the 45 day period,  
19 because it's in response to their suit. And the third one, the  
20 3522 case, is the one that really counts. That's the one that  
21 we filed within the 45 days of their notice to us. And that's  
22 the one that this Court has already selected as the lead case.  
23 So you don't have to bother with the declaratory judgment  
24 action, and you don't even have to bother, you can consolidate  
25 the other -- the two Warner Lambert cases, and as you said

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1 before, use the date as the date when we filed the 3522  
2 complaint.

3 MR. CALMANN: Your Honor, first of all factually what  
4 Mr. Francis just mentioned is not accurate. Your Honor did not  
5 select the later date. Mr. Barrett specifically requested that  
6 date, and Your Honor said, "Well, all right, that's fine."

7 When we got through the process, it was very clear that the  
8 2931 case, which was filed on the 15th after notices were  
9 received on the 14th, is absolutely a Hatch Waxman case. They  
10 filed it after receiving notice. That's what the statute says.  
11 That's what they did. They would like to ignore that case, go  
12 to the later case, and have that case be used for the 30 month  
13 stay. That further extends their monopoly position.

14 There's only one case that comes first, and that's the  
15 first in time. And in our Circuit, as Your Honor is aware, in  
16 the Federal Circuit the first filed suit rule applies  
17 generally. And I'm prepared to argue other aspects of the  
18 consolidation order as well, Your Honor. I didn't know you  
19 wanted to get into it now. But at least on that one issue,  
20 which is a very critical issue, we still have a problem.

21 MR. FRANCIS: Judge Lifland in his opinion dealt with  
22 the first filed and said that it doesn't matter here.

23 THE COURT: Okay. I will tell you, Mr. Calmann, Mr.  
24 Francis, as far as I'm concerned which one has priority, which  
25 one is going to function as the starting of the clock on Hatch

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1 Waxman is not something which has to be dealt with in this  
2 Consolidation Order. I'm gonna issue a Consolidation Order.  
3 I'm gonna draw my own Order. It is going to be consolidated  
4 sua sponte. And the Order is simply going to say they are  
5 consolidated for all purposes. I'm gonna put it under the  
6 lowest docket number that still survives. It will also provide  
7 that this consolidation has no effect on the priority or the  
8 timing under the Hatch Waxman Act in any way, shape or form.  
9 And you will be both left to bang your heads against the  
10 appropriate wall, but I'm not going to deal with this one any  
11 further. All right?

12 MR. CALMANN: Thank you, Your Honor.

13 THE COURT: Good. Next we have Mr. Haug, your Motion  
14 to Compel.

15 MR. HAUG: Thank you, Your Honor. If I may, I would  
16 like to break that up into two parts. I'm going to deal with  
17 the off label use so-called issue, and then Steve Amundson will  
18 deal with many of the other issues, if that's all right.  
19 Again, on the off label use issue, as I'm now referring to it,  
20 we are talking about the tablet case. We have our motion. We  
21 got the response from Warner Lambert on it last week. And I'd  
22 like to reply to that response very briefly. I think that most  
23 of the issues are well documented in the briefs.

24 However, a couple things. First of all, the tablet case  
25 is not the capsule case. They're different cases. There is no

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1 law of the case that applies to the tablet case. There is no  
2 collateral estoppel, res judicata or any such thing, in our  
3 view, that applies. They are different cases. They are two  
4 separate complaints filed by Warner Lambert. And as a result  
5 of that, Warner Lambert and PurePac have very different rights  
6 and duties and obligations that flow from both cases. They're  
7 different products. A capsule and a tablet, while they may  
8 seem to be the same but for shape, they're not. The FDA  
9 considers those two different products. They have two  
10 different approvals. They have two different 30 month periods  
11 that apply to them, and so on and so forth. They're different  
12 products.

13 Having said that, why is PurePac entitled to this  
14 information? What we did was, we subpoenaed Davis, Polk, which  
15 is another law firm representing Warner Lambert. We're not  
16 totally sure what they do other than they are representing  
17 Warner Lambert in connection with a suit, I think, by the  
18 Government and also a whistle blower case that's going on in  
19 Boston. We learned about them in part from documents that we  
20 were able to get from the Court in Boston. And, in fact, some  
21 of those documents are attached to our motion. I think as  
22 Exhibit A there is a disclosure there by Party Franklin. And  
23 that goes into a lot of the allegations that are extent in that  
24 investigation and in that case.

25 Now, we know that there are a number of boxes that have

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1 been collated, copied, marked for production, call it what you  
2 will, and in fact we believe produced already in that case.  
3 All we're asking for from Davis, Polk is the opportunity to  
4 look at those documents. Now, they're relevant in this case,  
5 in the tablet case, for a number of reasons. But the one  
6 reason that I would like to talk about with the Court here is  
7 they go directly to our unclean hands defense. They go  
8 directly to the arguments as to why Warner Lambert should be  
9 estopped from being able to prove its inducement infringement  
10 claim in this case based on their own activities in the  
11 marketplace. They're highly relevant to the equitable or the  
12 injunctive relief, if you will, that Warner Lambert is asking  
13 the Court for. Ultimately there will be a decision by the  
14 Court, with or without a jury, that using its own inherent  
15 powers and at its discretion will either grant an injunction,  
16 deny the injunction, or modify and do what it thinks is  
17 appropriate at that point in time.

18 We believe very strongly that we need to be able to show  
19 the Court all of the relevant evidence on the activities of  
20 Warner Lambert in creating the off label market. That is their  
21 claim against PurePac. They created the market through their  
22 own activities and now are saying that even though PurePac has  
23 no intent of trying to sell into that market, there is no  
24 document that says they're going to do that at all. And, in  
25 fact, there is evidence directly to the contrary. But they're

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1 going to ask the Court to infer, for whatever reasons, that  
2 PurePac is actively and knowingly engaging in infringement by  
3 inducing others to infringe, aiding and abetting the  
4 infringement of others. That's their case. I'm talking, of  
5 course, only about the 479 patent right now. That's their  
6 case.

7 So we're not confronted with, at trial, Warner Lambert  
8 will call either a Warner Lambert person or an expert who is  
9 presumably going to explain this market. He or she is going to  
10 talk about what Gabapentin is and what the market for  
11 Gabapentin is. And they're going to talk about the approved  
12 indication for treatment of epilepsy, which is a certain  
13 percentage. And then they're gonna talk about all this off  
14 label use.

15 THE COURT: Well, does all of this off label use -- as  
16 I understand it, the patent doesn't cover all of this off label  
17 use.

18 MR. HAUG: Correct.

19 THE COURT: It covers certain limited off label use.

20 MR. HAUG: Yes, the 479 patent is what we call  
21 treatment of neuro-degenerative disease, which depending upon  
22 which data you might look at, it might be as little as 2%, 4%.  
23 But that's a factual question as to how much of the off label  
24 use is directed to the treatment of neuro-degenerative diseases  
25 versus other things which are outside the scope of the 479

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1 patent. So that all is a factual question. And the important  
2 point I'm trying to make, though, is that whoever this witness  
3 is, or however Warner Lambert puts this evidence into the case,  
4 we have a right to discovery in order to prepare ourselves to  
5 cross examine that witness or that evidence. And right now we  
6 can't do that. And that's a serious problem.

7 And, again, what kind of evidence are we looking for? You  
8 know, we did talk about this clearly. Obviously Your Honor  
9 ruled in the capsule case. That's no secret and it's all in  
10 the papers. And the question at one point was asked, you know,  
11 why do we care about the FDA finding Warner Lambert has done  
12 something improper or not? Well what we really care about is  
13 the representations that Warner Lambert has made to the FDA or  
14 others, whether it's in another law suit to another Court or in  
15 a deposition or wherever it may be. What we care about are the  
16 representations that their people have made about whether they  
17 have or haven't promoted off label use and what the facts are,  
18 what off label use there is out there and how doctors are  
19 prescribing this drug, if they are, and what leads them to do  
20 that, and so on and so forth. That's what we're trying to get.  
21 We have a right to get that to prepare our defense on the  
22 inducement to infringe.

23 And, again, if Warner Lambert created the situation that  
24 they say is a necessary predicate to prove their infringement  
25 case, we believe we have a right to find out how they created

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1 that situation. And all we're asking for are the documents  
2 that they already have collected, documents which they've  
3 already produced. They're already -- they're together.  
4 There's no burden here.

5 THE COURT: Mr. Haug, I've been listening to you very  
6 carefully. And your papers talk about utilizing this material  
7 for an unclean hands defense. The argument you've just made  
8 doesn't focus on an unclean hands defense. It focuses on a  
9 contention that you've got a right simply in terms of cross  
10 examining witnesses who they may produce to explore how the off  
11 label market that they contend you'll infringe came into  
12 existence in the first place, as simply one element of  
13 exploring their case. Now, conceptually I've got to know  
14 whether your argument is one or the other or both.

15 MR. HAUG: The argument is to both, clearly. I do  
16 think -- I think one of the difficulties maybe I have here is  
17 unclean hands is a very -- you know, it's a very broad concept.  
18 And so, you know, I can't point to -- you know, I need to know  
19 what Mr. X said here and there in this document to go to the  
20 unclean hands defense. I don't know. That's --

21 THE COURT: Well let me ask you this.

22 MR. HAUG: -- what discovery is about.

23 THE COURT: Is, in the context of patent litigation,  
24 the concept of unclean hands indeed such a broad concept?

25 MR. HAUG: It's an equitable concept. I think fairly

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1 stated, most of the cases, substantially all of the cases to my  
2 knowledge, usually relate to how the patent was procured and  
3 equitable conduct. You know, whether or not certain product  
4 was or wasn't disclosed, and so on and so forth. Or, for  
5 example, certain information was or wasn't disclosed to the  
6 Patent Office, like a declaration is put in and they only put  
7 the good data in and not the bad data. Now, that's a good  
8 analogy though.

9 THE COURT: All right, but isn't that -- that's one  
10 category of unclean hands. And as I understand it, the other  
11 category of unclean hands ends up being largely analogous to  
12 certain types of anti-trust type activity. In short, improper  
13 efforts to broaden the monopoly conferred by the patent, and  
14 doing it in such a manner as to in fact broaden it beyond that  
15 authorized by the patent statutes. Correct?

16 MR. HAUG: Correct.

17 THE COURT: All right. Those are the two main  
18 categories that the unclean hands doctrine has fallen into with  
19 regard to patent litigation, at least. And now how do you  
20 analogize this particular claim with regard to those types of  
21 claims?

22 MR. HAUG: Well, I think on the patent side -- why  
23 don't we start with the easier one perhaps? I think on the  
24 unfair competition or anti-trust issue, clearly any activities  
25 done by Warner Lambert to either create or perpetuate or expand

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1 the monopoly that they have in a relevant market is highly  
2 relevant to the question of whether or not there is anti-trust.  
3 And there has been an anti-trust violation.

4 THE COURT: But that's not the contention here.

5 MR. HAUG: No, because we're not talking about the  
6 anti-trust claim in this --

7 THE COURT: Right.

8 MR. HAUG: -- motion. All right. Even though we have  
9 the decision from Judge Lifland yesterday, but that's for  
10 another day, that we bifurcate. So that's why our papers don't  
11 focus on it. On the patent side, again it's an equitable  
12 concept. You know, Warner Lambert is -- the only thing they're  
13 asking for on the 479 at this point, from my understanding, is  
14 an injunction both against PurePac from proceeding with the FDA  
15 in getting the final approval, and also if necessary to get the  
16 FDA from approving their ANDA. That's what they're asking for.  
17 And they're doing that --

18 THE COURT: Well, Ed --

19 MR. HAUG: -- on the basis --

20 THE COURT: -- Mr. Haug, that's because --

21 MR. HAUG: -- of infringement.

22 THE COURT: -- it's the only thing they can ask for,  
23 as a practical matter at this point. Correct?

24 MR. HAUG: Well, I guess so. I mean, you know, I  
25 don't know. The -- well, you know, I have to say by the time

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1 trial comes around I don't know. But it could change. But --

2 THE COURT: All right.

3 MR. HAUG: -- having said that, that's what they're  
4 asking for. And the trial here is going to involve a lot of  
5 legal issues. We had an argument here not too long ago about a  
6 lot of those issues, the validity and so on and so forth. But  
7 it's also going to involve equitable issues. And the Court,  
8 based on the evidence that it hears, is going to fashion a  
9 remedy, if it thinks any remedy is required or appropriate.  
10 And at that point in time we want to be able to have the Court  
11 consider all of the relevant evidence, which would certainly  
12 include what Warner Lambert has done to create the market that  
13 is a necessary predicate to prove their case of infringement.

14 THE COURT: Let me ask you a hypothetical. Let's  
15 forget about off label use of a method patent. All right? And  
16 let's take a hypothetical. Let's take hypothetically we have a  
17 saline solution which is just ordinary salt and water in a  
18 dispenser. And it just so happens that one potential use for  
19 this saline solution is to use it as a conductor in terms of  
20 applying stick-on electrodes for EKGs. All right? And, by the  
21 way, it's not totally hypothetical. Mr. Barrett's firm  
22 defended this case for years with two brothers suing each  
23 other, with Mr. Lerner, if I recall correctly, representing the  
24 Plaintiff brother in this particular case. So this may be a  
25 vague -- my recollection may be vague, but who knows? Mr.

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1 Francis is smiling. He may even remember this one.

2 MR. FRANCIS: I'm trying to forget it, Judge.

3 THE COURT: But at any rate, it was a method patent  
4 which covered the use of a saline solution to be applied in --  
5 constituting a conductor for the use of electrodes in EKGs.  
6 And the directions for using this method were printed on the  
7 package of Plaintiff's product. And in effect it was a package  
8 license for the method. All right? Which is if you purchased  
9 the bottle of saline, you got a license to use the method. The  
10 Plaintiff's brother decided to package the same saline  
11 solution. Did not list the instructions on it. But the  
12 contention was that the Plaintiff's brother knew perfectly well  
13 that when it was sold in those packages to the various  
14 institutions and providers that were involved, that they would  
15 know perfectly well what to do, which would be to practice  
16 Plaintiff's patent. There are some vague similarity so far.

17 Now, let me ask you this. If it turns out that the  
18 Plaintiff in this case had been paying bribes to a hospital's  
19 supply officers in order to induce sales of his saline and  
20 thereby, of course, increase the use of his patent, and thereby  
21 built his market, would that constitute an unclean hands  
22 defense by the Defendant alleged infringer?

23 MR. HAUG: Yes, in my judgment, absolutely. If you  
24 can prove --

25 THE COURT: And why is that?

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1 MR. HAUG: Because the Plaintiff is going to Court  
2 seeking equity. And he's seeking equity presumably because he  
3 has the right to do that. And any who seek equity must do  
4 equity. And all of those principles apply here. And if the  
5 Plaintiff was engaging in activity that is directly related to  
6 what he is now trying to get relief for, it is relevant. And  
7 the Court, I think, would have to consider that and weigh it as  
8 one of the factors that Courts weigh when they decide to give  
9 equity or not give equity. So I think to that extent it's a  
10 good example, quite frankly. And I certainly think as a stage  
11 of discovery, the Defendant should be able to probe that and  
12 find out exactly what did happen or didn't happen so that the  
13 parties can then decide at trial, or prior to trial, what is or  
14 isn't admissible at trial.

15 THE COURT: Why and how does the Plaintiff's marketing  
16 tactics bear a direct relationship to the right which he is  
17 seeking to assert?

18 MR. HAUG: Why?

19 THE COURT: Yes.

20 MR. HAUG: I think if it falls under -- looking at the  
21 Keystone Driller case, which is the Supreme Court case which  
22 both sides have actually cited in their briefs, I think that  
23 the key passage or key holding in that case is that the maxim  
24 of unclean hands does not apply where Plaintiff's misconduct is  
25 not directly related to the merits of the controversy. And so

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1 you have to look as to whether or not the challenged acts are  
2 directly related to the controversy. And I think that is a key  
3 question. Now in your hypothetical, you know, I --

4 THE COURT: How is it directly related to the  
5 controversy? The controversy is -- first of all, the right  
6 which is being asserted is a right to a monopoly created by the  
7 patent loss. Okay?

8 MR. HAUG: Yes..

9 THE COURT: There is no assertion that the Plaintiff  
10 engaged in inequitable conduct or unclean hands in connection  
11 with securing those rights. So, number one, we are  
12 automatically somewhat further afield than in the Keystone case  
13 in which, of course, there were misrepresentations in  
14 connection with essentially the securing of one of the three  
15 patents in the --

16 MR. HAUG: Right.

17 THE COURT: -- suit, if I recall correctly. So it  
18 doesn't relate to that. It doesn't relate to the use of the  
19 patent, per se. Why is it any different from someone who has a  
20 patent and who also is, say, a murderer?

21 MR. HAUG: Because the murder really is too distant  
22 from the question of infringement, even if the alleged  
23 infringer is the person who was murdered, I suppose. I mean  
24 it's just too distant. Here, Warner Lambert is saying there's  
25 an off label market. And everyone knows, including the

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1 Defendant, that if they're allowed to sell the product for any  
2 use, it's going to get sold for that off label use. And,  
3 therefore, we ask you, this Court, to enjoin them from selling  
4 it for anything including what they got an approval for.  
5 That's what this case is all about.

6 THE COURT: Let me throw this hypothetical at you.  
7 Let's take it out of the realm of a method patent. Let's have  
8 a product patent, a product patent for Gabapentin. Is that  
9 the correct pronunciation?

10 MR. FRANCIS: Very close.

11 MR. HAUG: Yes. There are --

12 MR. FRANCIS: Gabapentin.

13 MR. HAUG: -- a number of those.

14 THE COURT: I'll try Neurontin. It's easier. Let's  
15 say that there was still a product patent for Neurontin, which  
16 was in effect. And let's say that the Plaintiff's salesman in  
17 marketing that product started bribing doctors and hospital  
18 employees to sell the product. And then you come along and  
19 you're infringing. They seek an injunction. Is their bribery  
20 to sell the product where it's a product patent vulnerable to  
21 an unclean hands defense?

22 MR. HAUG: That's -- I think that's without a doubt  
23 further distant than the last hypothetical you gave me. I'm  
24 not sure that it would be, because I think that the patentee --  
25 excuse me, the Defendant can prove its affirmative defense of

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1 non-infringement on the basis of the product. All they have to  
2 do is look at the patent, get a legal interpretation of what  
3 the patent does or doesn't cover, and then compare that to the  
4 accused product. And presumably that is all you need to do to  
5 determine whether or not there is infringement. And so I don't  
6 know that whether the patentee at that point is bribing people  
7 to buy the product really adds much, if anything, to the  
8 infringement inquiry.

9       However, it might still be relevant from the standpoint  
10 that they're seeking an injunction. I mean they're asking the  
11 Court for an injunction. And the Court, in my understanding,  
12 certainly would have the power to say, "Yes, they are  
13 infringing. But, you know what? I'm not going to enjoin their  
14 use because you guys don't deserve an injunction because of all  
15 these acts that you did." I think the Court has the power, the  
16 legal and equitable power, to do that. And Courts have done  
17 that.

18       THE COURT: Are you aware of any Court which has  
19 recognized an unclean hands defense under the hypothetical  
20 which you have just described?

21       MR. HAUG: Where the people buy a product and they're  
22 not being held to unclean hands? Am I aware of a case that  
23 held that? No, no.

24       THE COURT: And let's face it, Mr. Haug, it's not in  
25 today's day and age, while I'm describing in rather blunt

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1 terms, all right -- we're all familiar with the various and  
2 sundry investigations which the Government engages in, in terms  
3 of methodologies of purveying drugs. And it's not a far  
4 fetched hypothetical, is it?

5 MR. HAUG: No, it's not -- that a drug company would  
6 bribe people? No, not at all. But --

7 THE COURT: We wouldn't call it a pure bribe. We  
8 would --

9 MR. HAUG: Honorarium.

10 THE COURT: -- label it perhaps an --

11 MR. HAUG: Call it an honorarium.

12 THE COURT: -- inducement which Medicaid and Medicare  
13 would frown upon, but --

14 MR. HAUG: Your Honor, if I may -- I don't mean to  
15 interrupt, but if I may, you know, if we're into -- to the  
16 extent we're talking about hypotheticals, you know, if the  
17 patentee in that scenario were to actually bribe a particular  
18 hospital, let's say, to the -- or bribe them and said, "We want  
19 you to call up this Defendant and buy a bunch of products from  
20 them." And they do, and they sell that product to that  
21 hospital, and then the patentee sues them for infringement, I  
22 think the fact that the patentee bribed the hospital to create  
23 the act of infringement is certainly actionable and would go to  
24 unclean hands and would act as an estoppel. I do. They  
25 created -- I mean it's like entrapment.

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1 THE COURT: Okay, but we're not talking about that.

2 We're talking about where -- my hypothetical is where the  
3 patentee offered an unlawful inducement to secure the purchase  
4 of its product and whether that constitutes an unclean hands  
5 defense.

6 MR. HAUG: I don't know of a case that holds that. I  
7 really don't. Whether it's been tried or there's a case saying  
8 that that can't be the case, I don't know either. I'd like to  
9 add one more thing. You know, from the standpoint of the  
10 patent itself, the invalidity in procurement of the patent, one  
11 of the key defenses that we have in this case on the 479 patent  
12 is invalidity. It is PurePac's position that the 479 patent is  
13 invalid because what it claims is false. It doesn't work. To  
14 put it another way, the patent says Gabapentin can be used to  
15 treat ALS. We have evidence in the case that without question,  
16 I believe, shows that it doesn't work for ALS.

17 Now, if Warner Lambert has been promoting Gabapentin for  
18 the treatment of ALS in the face of a patent that says --  
19 covers that use, but at the same time they are aware of  
20 evidence that it does not work, we think that, too, goes to  
21 unclean hands and would render the patent unenforceable, not to  
22 mention invalid.

23 THE COURT: Well --

24 MR. HAUG: And that is a key defense --

25 THE COURT: -- Mr. Haug --

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1 MR. HAUG: -- in the case.

2 THE COURT: -- you're losing me there. If in fact the  
3 patent has no utility, then it's invalid, right?

4 MR. HAUG: Correct.

5 THE COURT: And if you've got evidence establishing  
6 that which a trier of fact will accept, you're gonna win.

7 MR. HAUG: Yes.

8 THE COURT: Okay? Now, if you have evidence that they  
9 had information that the patent did not have utility at the  
10 time the patent was being processed, then we would indeed have  
11 inequitable conduct before the Patent Office. Correct?

12 MR. HAUG: I would -- yes.

13 THE COURT: All right. Are you suggesting to me that  
14 if, subsequent to the issuance of a patent, information comes  
15 forward which casts some doubts on whether or not the patent is  
16 -- has utility, that that is going to constitute unclean hands?

17 MR. HAUG: Yes, in the enforcement of that patent,  
18 absolutely. And it may even rise to the level of an anti-trust  
19 violation. Definitely. If you know your patent to be invalid  
20 and you continue to enforce it and try to enforce it after you  
21 have that knowledge, that is very definitely unclean hands.  
22 And it could, as I said, patent misuse. And it could rise to a  
23 level of an anti-trust violation.

24 THE COURT: Okay. Anything further you'd like to  
25 argue on this issue?

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1 MR. HAUG: No, I don't think so.

2 THE COURT: Mr. Francis, who is up --

3 MR. FRANCIS: Mr. Barrett is.

4 THE COURT: -- you or Mr. Barrett? Mr. Barrett?

5 MR. BARRETT: It shall be me, Your Honor, although in  
6 light of your excellent questions you posed to Mr. Haug, I'm  
7 not sure that I should proceed with an argument rather than  
8 just field your questions to me. But let me just start with  
9 one thing. Let me just paint the facts as Mr. Haug would like  
10 them here so we're all -- everybody's clear that we're on the  
11 same table. And that is what he is suggesting -- and these are  
12 putting these facts in the best light for Mr. Haug's argument -  
13 - is that somehow Warner Lambert went out and created a market  
14 for a drug and a particular use. Actually created a market for  
15 this particular use. And did so illegally. Then taking a  
16 patent that it had covering that particular use, it has sued  
17 PurePac for patent infringement. And that act of illegally  
18 creating the market for the very act that Mr. Haug's client is  
19 accused of infringing, is indeed an act of unclean hands which  
20 taints the patent and its enforcement.

21 Now I think that's painting them in the best light for Mr.  
22 Haug. Now it's not to mean that those facts are true.  
23 Certainly things such as Warner Lambert -- no drug company can  
24 create a market for a drug. Doctors do that. Doctors and  
25 patients do that. Certainly drug companies can promote and

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1 make a market larger, but they can't generate from scratch a  
2 market for a drug, I don't believe. And I don't know of any  
3 instance where they've done that.

4 Second, we're not talking here about any suggestion that  
5 there's any potential or even allegation of illegal promotion  
6 with respect to this particular treatment. So that fact is not  
7 a given. But putting the facts in the best light for Mr. Haug,  
8 that's what he's suggesting. And I believe Your Honor is going  
9 to agree with me when I say that that has absolutely no  
10 precedent in the case law. It is a totally unprecedented  
11 suggestion that those kinds of acts by a drug company or a  
12 marketer could somehow lead to an unclean hands defense, making  
13 the patent unenforceable.

14 I like your -- the way you broke apart the possibility  
15 that this defense could have something to do with some broader  
16 anti-trust allegations, monopolization. Somehow this could  
17 play some kind of a theory. I think that's where you were  
18 going there. But this motion has nothing to do with anti-trust  
19 discovery. The anti-trust issues in this case have been  
20 stayed, including discovery. And Mr. Haug knows that. But he  
21 is, as Your Honor understands, he is seeking this discovery for  
22 his patent case. So he's got to tie it into the aspect of  
23 unclean hands as it totally relates to the patent. Your Honor  
24 understands the Keystone case, the case that he keeps citing  
25 has nothing to do with this kind of activity. It relates to

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1 the standard unclean hands that relates to the obtaining of a  
2 patent, doing bad things before the Patent Office.

3       Indeed if there is any precedent, I think that's that 3rd  
4 Circuit case in Ciba-Geigy vs. Bolar, although a trademark  
5 case, has some pertinence here because it was an attempt to tie  
6 in potentially illegal acts by the enforcer of the property  
7 right as an unclean hands defense. And the Courts rejected it  
8 and said the two things are totally separate. Whether Achieva  
9 markets its drug illegally or promotes it for this second step  
10 instead of the third step, and in fact the suggestion is there  
11 that they may have created some kind of infringing market  
12 there, that they then sued Bolar on -- there was no tie-in that  
13 made it a viable unclean hands defense. So I think the  
14 precedent clearly goes in the other direction.

15       THE COURT: Let me ask you this. You just stated  
16 earlier that your view of the record indicates that there is no  
17 evidence or no suggestion that there was -- or no issue that  
18 there was any improper promoting of Neurontin for off label use  
19 with regard to the off label uses that are covered by the  
20 patent?

21       MR. BARRETT: Yes, Sir.

22       THE COURT: Okay.

23       MR. BARRETT: Based upon the documents that Mr. Haug  
24 has been pointing to that have led him to this new defense.

25       THE COURT: Okay.

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1 MR. BARRETT: And by that I mean Mr. Franklin's --  
2 this started off, Your Honor, with the FDA letter which they  
3 got a long time ago where they learned all about this. Now  
4 they've -- I think we've made the point in our brief and I  
5 won't push it again here, that they didn't learn anything new  
6 here from Mr. Franklin's complaint. But Mr. Franklin did file,  
7 and it's attached to Mr. Amundson's affidavit, a summary of his  
8 allegations. Now it doesn't look like Mr. Franklin wrote -- it  
9 looks very much like a lawyer-written document that Mr.  
10 Franklin then agreed to. But if you look at it, he does talk  
11 about the various activities that he thinks that salesmen for  
12 Warner Lambert were doing some bad things about. And he  
13 specifies them. And none of them have anything to do with the  
14 particular diseases that we indeed have highlighted as being  
15 the treatment of neuro-degeneration.

16 You know, in response to Mr. Haug's suggestion that -- our  
17 expert in this case has gone through and found out that doctors  
18 have been prescribing this drug for treating neuro-  
19 degeneration. And the data from surveys has shown a certain  
20 percentage of sales. So I -- it seems to fly in the face of  
21 Mr. Haug saying that this drug has no utility. It just doesn't  
22 seem to -- the two can't seem to exist in the same arena. And  
23 if he wants to push this utility argument with respect to a  
24 validity, like Your Honor suggested, I think that makes sense.  
25 But to try to tie it into infringement seems to be -- fly in

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1 the face of the fact that if there are -- if, in fact, he is  
2 correct and there's no utility, then we will not be able to  
3 prove any infringing uses. And there should be no problem for  
4 Mr. Haug in that regard.

5 I -- any other questions I could field from Your Honor? I  
6 think it's important that -- I don't want to go back to the  
7 fact that they had an opportunity in the earlier case to get  
8 into this unclean hands defense. And our suggestion that this  
9 is an afterthought that they didn't think of -- I think it's  
10 clearly an afterthought. But I don't think Your Honor is gonna  
11 rule on that. I don't think he needs to use that as a handle  
12 on which to decide whether or not to produce these documents.

13 But it's important -- Mr. Haug is wrong when he says these  
14 are two separate cases. These were almost one case. We had  
15 asked Your Honor to consolidate these two cases. They are  
16 identical subject matter in every way. The infringement  
17 allegations, the patent invalidity allegations are identical in  
18 each case. One product accused is a capsule, one is a tablet.  
19 Most often those kinds of things are in one case. This  
20 happened to be in two cases. It wasn't consolidated. But it  
21 wasn't consolidated with the understanding that the kind of  
22 discovery that was gonna be used, and going to be completed in  
23 the tablet case, and the extra time that it was gonna go on,  
24 was going to be a little bit of clean-up discovery to clean up  
25 the very narrow issues that made that case differently. I'm

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1 really sort of getting into the second aspect of our motion,

2 Your Honor --

3 THE COURT: All right, we'll continue --

4 MR. BARRETT: -- which is almost defending why we  
5 always seem to be under the gun here as not having provided  
6 discovery to PurePac. So maybe I ought to hold off on that.

7 THE COURT: Mr. Haug, anything further?

8 MR. HAUG: Just one last comment. And maybe it's just  
9 a period on this. We have been here many times over -- it's  
10 going on -- I don't want to tell you how long we've been at  
11 this, but it's almost two and half full years. We've been to  
12 the Court many times asking for this, that and the other thing.  
13 In this instance I really -- PurePac is of the view that this  
14 goes to the heart of their infringement case and this issue's  
15 not going to go away. And regardless of the ruling, it's going  
16 to rear its head again as we head towards trial. And it's  
17 going to continually be argued at trial. And I don't know  
18 where it's gonna go from there.

19 And I would leave the Court with this. I am looking ahead  
20 to the opening or closing arguments to a jury or Court, Judge.  
21 And on the one hand, Warner Lambert is going to be saying the  
22 evidence, the circumstantial evidence shows that PurePac is  
23 actively aiding and abetting infringement because they're  
24 putting a drug into commerce based on an approval from the FDA.  
25 And whether they do anything more or not, and even though they

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1 wrote a letter to the entire industry saying, "Don't prescribe  
2 it for anything but for what it's approved," they're still  
3 guilty of intentional infringement. That's what they will  
4 argue based on the circumstantial evidence they present.

5 I believe PurePac must be able to defend itself and say  
6 apart from denying those allegations, the jury or Court must  
7 also consider how that market was created and what Warner  
8 Lambert had to do with it. And they made a conscious decision  
9 to create that market, enhance that market, and now they're  
10 using their patent to further that monopoly they already have  
11 and to keep generic competition off for as long as they  
12 possibly can. That's what this case is all about. Thank you,  
13 Your Honor.

14 THE COURT: Okay, thank you.

15 MR. BARRETT: Your Honor, I need to make one point  
16 that I promised Ms. Smith, who isn't here today, that I would  
17 make in this argument. I had forgotten before. But it ties in  
18 perfectly here. And that is that Mr. Haug is saying that what  
19 he needs is this group of documents. And that's all Your Honor  
20 has to rule on, a simple little group of documents, all been  
21 collected. And that's all they need and the matter is put to  
22 rest. This group of documents was generated and collected back  
23 in 1996. If Mr. Haug is serious about pursuing this defense  
24 and he's allowed to do it, he's gonna need an update of those  
25 documents. He's gonna need to go and get all of the current

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1 documents to show that we are currently doing what he's being  
2 accused of infringement. Something we did three or four years  
3 ago, if we're not doing it now, doesn't make much relevance  
4 anyway, even under his theory. So I'm simply suggesting that  
5 this is simply the tip of the iceberg, opening the Pandora's  
6 box, however we want to phrase it. It really is more than Mr.  
7 Haug is suggesting, Your Honor. Thank you.

8 THE COURT: All right, thank you. As counsel know,  
9 this particular application seeks the production of documents  
10 from a third party custodian of material relating to the  
11 exploration by the FDA and potentially material relating to a  
12 private lawsuit which in Defendant's view would indicate that  
13 the Plaintiff has engaged in improper conduct in promoting the  
14 off label use of the drug, Neurontin. Defendant contends that  
15 the production of this material will support and establish an  
16 unclean hands defense by demonstrating that the Plaintiff has  
17 engaged in inequitable behavior in connection with the  
18 promotion of this off label usage of its product. In  
19 particular, Defendant contends that since Plaintiff's patent is  
20 a method patent, which is only violated by use of Neurontin to  
21 treat neuro-degenerate -- is that the correct pronunciation --

22 MR. HAUG: Neuro-degenerative.

23 THE COURT: -- neuro-degenerative diseases, that the  
24 Plaintiff's alleged improper promotion of that off label market  
25 should bar it from asserting its rights under the patent

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1 against the Defendant. Defendant further claims that since it  
2 is Plaintiff's theory that any sale of Neurontin by the  
3 Defendant would necessarily, at least in part, result in its  
4 use by practitioners in a manner which violates the patent,  
5 because of the manner in which Plaintiff has promoted its off  
6 label use, that it's particularly appropriate to apply the  
7 doctrine of unclean hands.

8 Plaintiff relies on the Supreme Court's decision in  
9 Keystone Driller Company vs. General Excavator Company, 290  
10 U.S. 240 {paren.} (1933) {closed paren.} to support its  
11 contention that the unclean hands doctrine applies in this  
12 context. This Court is not persuaded. PurePac has cited no  
13 cases which are factually analogous to that before the Court.  
14 It is indeed clear that there are no cases which applied this  
15 doctrine to circumstances which are even close to that  
16 presented in this matter.

17 As noted by the Court in Republic Molding Corporation vs.  
18 BW Photo Utilities, reported at 319 Fed. 2nd 347, 9th Circuit,  
19 1963, {quote} "Where unclean hands has been asserted to bar a  
20 claim of infringement, it has usually been because the patent  
21 was fraudulently obtained (citations omitted) or there had been  
22 a concealment of evidence amounting to a fraud on the Court  
23 (citation omitted) or perhaps more remotely the patent was  
24 being misused as for example in violation of the Sherman Act."  
25 This particular scenario fits into none of those categories.

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1 And indeed as the Court in Keystone Driller noted, {quote}  
2 "What does seem clear" -- I'm sorry, strike that quote and  
3 instead refer to Republic Moldings Corporation vs. BW Photo  
4 Utilities. {Quote} "What does seem clear is that misconduct in  
5 the abstract, unrelated to the claim to which it's asserted as  
6 a defense, does not constitute unclean hands. The concept  
7 invoking the denial of relief is not intended to serve as a  
8 punishment for extraneous transgressions, but instead is based  
9 upon considerations that make for the advancement of ripe  
10 injustice. What is material is not that the Plaintiff's hands  
11 are dirty, but that he dirtied them in acquiring the right he  
12 now asserts or that the manner of dirtying renders inequitable  
13 the assertion of such rights against the Defendant. As  
14 Professor Chaffee suggests, we should not by this doctrine  
15 create a rule comparable to that by which a careless motorist  
16 would be able to defend a subsequent personal injury suit by  
17 proving that the pedestrian had beaten his wife before leaving  
18 his home."

19 This Court finds that the assertion of an unclean hands  
20 defense under the circumstances contended by Defendant indeed  
21 amounts to an assertion which is similar to that involving the  
22 careless motorist. There is no assertion here that the patent  
23 was attained by improper means or means which constitute a  
24 basis for finding unclean hands. There is no assertion here  
25 that this litigation before the Court involves such conduct.

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1 All that exists is an assertion that the Plaintiff in the  
2 course of marketing its product in Defendant's view has  
3 violated guidelines and procedures issued by the FDA  
4 controlling the manner in which products may be promoted for  
5 off label usage.

6 It is rather clear to the Court, from prior proceedings  
7 before it, that that particular area is at a minimum a rather  
8 arcane and difficult area of law. It does not strike the Court  
9 that whether or not Plaintiff has been able to properly  
10 navigate that particular thicket constitutes a basis for  
11 determining whether or not its patent should or should not be  
12 enforced in this matter.

13 It is Defendant's contention that Plaintiff's overall  
14 theory has substantial problems, since in effect, as I  
15 understand it, Defendant is contending that Plaintiff asserts  
16 contributory or reducing infringement regardless of whether or  
17 not the Defendant has any intention of engaging in such  
18 conduct. That may very well be a litigable issue. But what is  
19 not a litigable issue is whether or not the off label promotion  
20 involved in the FDA proceedings has any relevance to this  
21 lawsuit. For those reasons, the Court will deny Defendant's  
22 application to compel the documents in question. Let's proceed  
23 to your next claims, which I think we can move along a little  
24 bit quicker on.

25 MR. AMUNDSON: Good morning, Your Honor. The next

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

In re Gabapentin Patent Litigation  
\_\_\_\_\_

)  
) MDL No. 1384  
) Master Docket No.  
) 00-CV-2931 (FSH)  
)  
) **This Filing Applies To:**  
) Teva Defendants  
) C.A. No. 00-CV-4168 (FSH)  
) C.A. No. 00-CV-4589 (FSH)  
)  
) IVAX Defendants  
) C.A. No. 00-CV-6073 (FSH)  
) C.A. No. 01-CV-0193 (FSH)  
) C.A. No. 01-CV-1537 (FSH)  
)  
) Eon Defendants  
) C.A. No. 01-CV-2194 (FSH)  
)

**[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION TO STRIKE CERTAIN  
AFFIRMATIVE DEFENSES OF TEVA, IVAX, AND EON DEFENDANTS**

THIS MATTER having been brought before the Court by application of plaintiffs Pfizer Inc., Warner-Lambert Company LLC, Gödecke GmbH, and Pfizer Pharmaceuticals LLC (“Plaintiffs”), for an Order granting Plaintiffs’ Motion to Strike Certain Affirmative Defenses of Teva, IVAX, and Eon Defendants; and the Court having considered all papers submitted herewith, including the accompanying Memorandum of Law and Declaration of John J. Francis, Jr.; and for good cause shown,

IT IS on this \_\_\_\_ day of \_\_\_\_\_, 2008, hereby

ORDERED THAT the Fourth Affirmative Defense of Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, “Teva”) of unclean hands and Fifth Affirmative Defense of patent misuse are hereby stricken from Teva’s Answer to Plaintiffs’ First Amended and Supplemental Complaint in C.A. No. 00-CV-4168 (FSH) and C.A. No. 00-CV-4589 (FSH) under Fed. R. Civ. P. 12(f);

IT IS FURTHER ORDERED THAT the Fourth Affirmative Defense of Zenith Laboratories, Inc. (now known as IVAX Pharmaceuticals NV, Inc.), Zenith Goldline Pharmaceuticals, Inc. (now known as IVAX Pharmaceuticals, Inc.), and IVAX Corp. (collectively, “IVAX”) of unclean hands and Fifth Affirmative Defense of patent misuse are hereby stricken from IVAX’s Answer to Plaintiffs’ First Amended and Supplemental Complaint in C.A. No. 00-CV-6073 (FSH), C.A. No. 01-CV-0193 (FSH), and C.A. No. 01-CV-1537 (FSH) under Fed. R. Civ. P. 12(f); and

IT IS FURTHER ORDERED THAT the Fifth Affirmative Defense of Eon Labs Manufacturing, Inc. (now known as Eon Labs, Inc.) and Sandoz, Inc. (collectively, “Eon,” and together with Teva and IVAX, “Defendants”) of unclean hands is hereby stricken from Eon’s

Answer to Plaintiffs' First Amended and Supplemental Complaint in C.A. No. 01-CV-2194  
(FSH) under Fed. R. Civ. P. 12(f).

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FAITH S. HOCHBERG, U.S.D.J.